

**510(k) Summary**

MAY - 7 2007

**Preparation Date:** March 23, 2007

**Applicant/Sponsor:** Biomet Trauma (formerly known as EBI Trauma)  
100 Interpace Parkway  
Parsippany, NJ 07054

**Contact Person:** Debra L. Bing  
Director, Regulatory Affairs  
Biomet Trauma  
973.299.9300

**Proprietary Name:** Growth Control Plating System

**Common Name:** Pediatric orthopedic implant

**Classification Name:** Single/multiple component metallic bone fixation appliances and accessories, 21 CFR §888.3030, HRS

**Legally Marketed Devices To Which Substantial Equivalence Is Claimed:**

Guided Growth Plate K031493 University of Utah School of Medicine

**Device Description:** The Growth Control Plating System consists of plates and screws, all of which are comprised of Ti-6Al-4V.

**Intended Use:** The Growth Control Plating System is designed for redirecting the angle of growth of long bone(s) in pediatric patients. This is useful for gradually correcting angular deformities in pediatric patients with an open physis. Specific conditions/ diseases for which the device will be indicated include valgus, varus or flexion, extension deformities of the knee (femur and/or tibia); valgus, varus or plantar flexion deformities of the ankle, valgus or varus deformities of the elbow, as well as radial or ulnar deviation, flexion or extension deformities of the wrist (radius).

**Summary of Technologies:** The technological characteristics of the Growth Control Plating System are the same as, or similar to, the predicate device.

**Non-Clinical Testing:** Non-clinical laboratory testing was performed to determine substantial equivalence. The results indicated that the device was functional within its intended use.

**Clinical Testing:** None provided as a basis for substantial equivalence.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Biomet Trauma  
% Ms. Susan Alexander  
Regulatory Specialist  
Biomet Manufacturing Corp.  
P.O. Box 587  
Warsaw, Indiana 46581-0587

MAY - 7 2007

Re: K070823  
Trade/Device Name: Growth Control Plating System  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories  
Regulatory Class: II  
Product Code: HRS  
Dated: March 23, 2007  
Received: March 26, 2007

Dear Ms. Alexander:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Barbara Melkerson" with "MD" in parentheses, and a small "106" written below the signature.

Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K070823

Device Name: Growth Control Plating System

### Indications For Use:

The Growth Control Plating System is designed for redirecting the angle of growth of long bone(s) in pediatric patients. This is useful for gradually correcting angular deformities in pediatric patients with an open physis. Specific conditions/diseases for which the device will be indicated include valgus, varus, or flexion extension deformities of the knee (femur and/or tibia); valgus, varus or plantar flexion deformities of the ankle, valgus or varus deformities of the elbow, as well as radial or ulnar deviation, flexion or extension deformities of the wrist (radius).

Prescription Use X AND/OR Over-The-Counter Use NO  
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Darlene Bruehl  
(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

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